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August 21, 2009

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**Message:**

Attached please find draft claims as discussed on Thursday, August 20, 2009.

Jacqueline Benn

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Swain <i>et al.</i>	Confirmation No.:	9609
Application No.:	10/647,071	Art Unit:	1639
Filed:	August 22, 2003	Examiner:	Steele, Amber D.
For:	HAPTEN-CARRIER CONJUGATES FOR USE IN DRUG-ABUSE THERAPY AND METHODS FOR PREPARATION OF SAME	Attorney Docket No.:	11662-003-999
		CAM No.:	526624-999003

**DRAFT PROPOSED AMENDMENTS TO THE CLAIMS**

Patent Examiner Amber D. Steele  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Examiner Steele:

Further to our teleconference of August 20, 2009, Applicants submit a draft proposed amendments to the claims herewith.

**Draft Proposed Amendments to the Claims** are reflected in the Listing of the Claims that begins on page 2 of this paper.

**Remarks** begin on page 5 of this paper.

Application No. 10/647,071  
Attorney Docket No. 11662-003-999

**DRAFT PROPOSED AMENDMENTS TO THE CLAIMS**

This Listing of the Claims will replace all prior versions, and listings of the claims in the application.

**Listing of the Claims:**

1.-124. (Canceled)

125. (Currently Amended) A pharmaceutical composition comprising a hapten-carrier conjugate, said pharmaceutical composition comprising

at least one hapten which is nicotine or a nicotine derivative, wherein the nicotine derivative is not cotinine; and

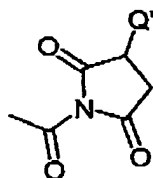
at least one carrier which is a pseudomonas exotoxin,

and wherein said hapten and said carrier are linked by a branch ~~selected from the group of~~ chemical moieties identified by CJ reference number ~~consisting of,~~ and wherein the branch is:

CJ 0	Q
CJ 1	(CH <sub>2</sub> ) <sub>n</sub> Q
CJ 1.1	CO <sub>2</sub> Q
CJ 2	OCO(CH <sub>2</sub> ) <sub>n</sub> Q
CJ 2.1	OCOCH=Q
CJ 2.2	OCOCH(O)CH <sub>2</sub>
CJ 2.3	OCO(CH <sub>2</sub> ) <sub>n</sub> CH(O)CH <sub>2</sub>
CJ 3	CO(CH <sub>2</sub> ) <sub>n</sub> COQ
CJ 3.1	CO(CH <sub>2</sub> ) <sub>n</sub> CNQ
CJ 4	OCO(CH <sub>2</sub> ) <sub>n</sub> COQ
CJ 4.1	OCO(CH <sub>2</sub> ) <sub>n</sub> CNQ
CJ 5	CH <sub>2</sub> OCO(CH <sub>2</sub> ) <sub>n</sub> COQ
CJ 5.1	CH <sub>2</sub> OCO(CH <sub>2</sub> ) <sub>n</sub> CNQ
CJ 6	CONH(CH <sub>2</sub> ) <sub>n</sub> Q
CJ 7	Y(CH <sub>2</sub> ) <sub>n</sub> Q
CJ 7.1	CH <sub>2</sub> Y(CH <sub>2</sub> ) <sub>n</sub> Q
CJ 8	OCOCH(OH)CH <sub>2</sub> Q
CJ 8.1	OCO(CH <sub>2</sub> ) <sub>n</sub> CH(OH)CH <sub>2</sub> Q
CJ 9	OCOC <sub>6</sub> H <sub>5</sub>

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CJ 10



, wherein Q' is a modified

protein;

CJ 11 YCO(CH<sub>2</sub>)<sub>n</sub>COQ; and/or  
 CJ 11.1 CH<sub>2</sub>YCO(CH<sub>2</sub>)<sub>n</sub>COQ,

and wherein for each branch, n is independently an integer; Y is S, O, or NH; and Q is selected from the group consisting of:

- (i) —H;
- (ii) —OH;
- (iii) —CH<sub>2</sub>;
- (iv) —CH<sub>3</sub>;
- (v) —OCH<sub>3</sub>;
- (vi) —COOH;
- (vii) a halogen;
- (viii) an activated ester or esters, such as 2-nitro-4-sulfophenyl ester and N-oxy succinimidyl ester;
- (ix) a group or groups reactive toward the carrier, such as a mixed anhydride, acyl halide, acyl azide, alkyl halide, N-maleimide, imino ester, isocyanate, and isothiocyanate;
- (x) the carrier; and/or
- (xi) another "branch" identified by its "CJ" reference number;

~~and wherein said hapten-carrier conjugate elicits nicotine-specific antibodies in a human.~~

126. (Previously Presented) The pharmaceutical composition of claim 125, wherein n is from 3 to 20.

127. (Canceled)

128. (Previously Presented) The pharmaceutical composition of claim 125, wherein greater than one hapten is coupled to the carrier.

129. (Canceled)

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130. (Canceled)

131. (Previously Presented) The pharmaceutical composition of claim 125, further comprising a pharmaceutically acceptable excipient.

132. (Presently Amended) The pharmaceutical composition of claim 125, further comprising an adjuvant.

133. (Previously Presented) The pharmaceutical composition of claim 132, wherein the adjuvant is alum or RIBI adjuvant.

134. (Previously Presented) The pharmaceutical composition of claim 133, wherein the adjuvant is alum.

135. (Previously Presented) The pharmaceutical composition of claim 134, wherein the alum is aluminum hydroxide or aluminum phosphate.

136. (Previously Presented) The pharmaceutical composition of claim 125, further comprising an auxiliary agent or supplementary active compound.

137. (Previously Presented) The pharmaceutical composition of claim 125 which is suitable for parenteral administration to a human.

138. (Previously Presented) The pharmaceutical composition of claim 125 which is suitable for oral, dermal or topical administration to a human.

139. (Canceled)

140. (Canceled)

141. (Canceled)

142. (Previously Presented) The pharmaceutical composition of claim 125, further comprising a pharmaceutically acceptable excipient.

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Attorney Docket No. 11662-003-999

REMARKS

Applicants propose the following draft amendments to the claims in order to place the claims in condition for allowance.

The phrase objected to by the Examiner, *i.e.*, "elicits nicotine-specific antibodies in a human," in the Office Action dated July 28, 2009, has been deleted from the claims. Thus, the amended claims obviate the rejections under 35 U.S.C. § 112.

The claims are also amended to specify that the hapten is *not* cotinine, and thus, are patentable over U.S. Patent No. 5,164,504 to Walling *et al.* ("Walling") of record, which was cited by the Examiner in Office Actions throughout the prosecution of the present application. Support for this amendment can be found in the specification as filed, for example, at p. 16, *ll* 8-10, p. 38, *ll* 16-17, and Figure 19, which identifies cotinine, *sic* "COTINE," and other metabolites of nicotine as useful in the preparation of the conjugates. Such an amendment is permitted because "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims" (M.P.E.P. § 2173.05(i), 8<sup>th</sup> Ed., Revision 7, July 2008).

The chemical branches, which link the hapten to the carrier, and the group Q, which make up some of the branches, are amended to be claimed in the alternative, eliminating the need for Markush language (*see* M.P.E.P. §2173.05(h) 8<sup>th</sup> Ed., Revision 7, July 2008).

Applicants respectfully request that the Examiner consider the draft proposed amendments to the claims submitted herewith and invite the Examiner to contact the undersigned attorney to discuss the same.

Respectfully submitted,

Date: August 21, 2009

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